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10/087,449	02/28/2002	Michael L. Blomquist	4176.25US01	9068

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EXAMINER

NORTON, JENNIFER L

ART UNIT	PAPER NUMBER
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2121

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,449	Applicant(s) BLOMQUIST, MICHAEL L.	
	Examiner Jennifer L. Norton	Art Unit 2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-7,9-11,26 and 27 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-7,9-11,26 and 27 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/8/11,9/9/11</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The following is a **Final Office Action** in response to the Amendment/Remarks received on 12 August 2011. Claims 8, 12-25, 28 and 29 have been cancelled. Claims 1-7, 9-11, 26 and 27 are pending in this application.

Information Disclosure Statement

2. The information disclosure statement filed 9 September 2011 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7, 9-11, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0114836 A1 (hereinafter Estes) in view of WIPO Publication No. 02/11049 A2 (hereinafter Blomquist).

4. As per claim 1, Estes substantially teaches Applicant's claimed invention. Estes teaches the elements of a method of programming an ambulatory infusion pump (Fig. 1, element 100) from a computer (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the ambulatory infusion pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program being driven by operating parameters (pg. 3, par. [0032] and [0033]), the method comprising:

generating data (Fig. 3A, element 300) on an interface displayed by the computer the computer having a computer peripheral (col. 6, par. [0054]),

the data (Fig. 3A) contained in a row (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), and

each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3); and

downloading the operating parameters into the pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300) by:

transmitting the operating parameters over a communication link (Fig. 2, element 134) from the computer to the pump (pg. 3, par. [0034]).

Not explicitly taught is generating a table on a user interface displayed by the computer the computer having a computer peripheral, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating

parameter for the delivery program; entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral; returning the operating parameters over a communication link from the pump back to the computer; and verifying that the operating parameters transmitted from the computer to the pump match the operating parameters returned from the pump to the computer.

However Blomquist, in an analogous art of configuring pumps for infusing fluids, teaches the missing limitations of generating a user interface displayed by the computer the computer having a computer peripheral (pg. 6, lines 31-34 and pg. 7, lines 1-2), the table (Fig. 8, element 810 and 812; i.e. table) containing a row (Fig. 8, element 814 and 816; i.e. an array of the table), the row having a plurality of cells (i.e. fields), each cell in the row relating to a different operating parameter for the delivery program (pg. 16, lines 28-34 and pg. 17, lines 1-32; i.e. each field of the array in the table comprising one of a plurality of operating parameters); entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral (pg. 3, lines 31-32, pg. 5, lines 29-32, pg. 6, lines 34, pg. 7, line 1-2, pg. 16, lines 28-34, pg. 17, lines 1-32 and Fig. 1, element 104; i.e. the user entering an operating parameter via input devices into one of a plurality of fields of the array); returning the operating parameters over a communication link from the pump back to the computer (pg. 24, lines 6-15); and verifying that the operating parameters transmitted from the computer to the pump

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match the operating parameters returned from the pump to the computer (pg. 24, lines 6-15) for the purpose of generating and verification of operational data that is download to an infusion pump (Blomquist: pg. 3, lines 31-34 and pg. 4, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Estes to include the addition of the limitations of generating a table on a user interface displayed by the computer the computer having a computer peripheral, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral; returning the operating parameters over a communication link from the pump back to the computer; and verifying that the operating parameters transmitted from the computer to the pump match the operating parameters returned from the pump to the computer to eliminate the need for different pumps to be repeatedly programmed with the same sets of program data, thus providing efficiency and increased automation (Blomquist: pg. 1, lines 32-33 and pg. 2, lines 1-2).

5. As per claim 2, Estes does not explicitly teach the act of generating a table further comprising generating a table, the table comprising a plurality of rows, each row

relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

The combination of Estes in view of Blomquist teaches generating a table, the table comprising a plurality of rows (Fig. 8, element 816), each row relating to a different set of operating parameters (i.e. a record), each set of operating parameters defining a different delivery schedule for the pump (pg. 17, lines 5-32) for the purpose of generating and verification of operational data that is download to an infusion pump (Blomquist: pg. 3, lines 31-34 and pg. 4, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Estes to include the addition of generating a table, the table comprising a plurality of rows, each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump to eliminate the need for different pumps to be repeatedly programmed with the same sets of program data, thus providing efficiency and increased automation (Blomquist: pg. 1, lines 32-33 and pg. 2, lines 1-2).

14. As per claim 3, Estes teaches as set forth above the table comprising at least one cell within each row relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

15. As per claim 4, Estes teaches as set forth above downloading the operating parameters into memory (Fig. 2, element 106) on the pump (pgs. 3-4, par. [0035]; downloading the operating parameters from Fig. 2, element 132), the pump being programmed with a delivery schedule (pgs. 3-4, par. [0035]).

16. As per claim 5, Estes teaches as set forth above running the delivery program and, executing the operating parameters (pg. 8, par. [0073] and Fig. 6).

17. As per claim 6, Estes teaches as set forth above the method further comprising: downloading all of the operating parameters to the infusion pump (pgs. 3-4, par. [0035] and Figs. 3A, element 300); and
storing the operating parameters in the memory (pgs. 3-4, par. [0035]).

18. As per claim 7, Estes teaches as set forth above selecting one unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

6. As per claim 9, Estes substantially teaches Applicant's claimed invention. Estes teaches an apparatus (Fig. 2, element 132) for programming an infusion pump (pgs. 2-3, par. [0027]), pgs. 3-4, par. [0034] and [0035] and Fig. 1, element 100), the

pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program programmed to process operating parameters (pg. 3, par. [0032] and [0033]), the operating parameters defining operation of the pump (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), the apparatus comprising:

- a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop);
- a data entry device (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop); and
- a processor in data communication with the data port and the data entry device (pg. 3, par. [0034]; e.g. PC, laptop), data (Fig. 3A, element 300), the data contained in a row, the row having a plurality of cells (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3);

- (b) display the data in one or more of the cells (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300); and

- (c) download the received operating parameters displayed (col. 6, par. [0054]) in the cells to the infusion pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300) by:

- transmitting the operating parameters over a communication link (Fig. 2, element 134) from the computer to the pump (pg. 3, par. [0034]).

Not explicitly taught is generating a table on a user interface, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; receive at least one operating parameter directly from the data entry device returning the operating parameters over a communication link from the pump back to the apparatus; and verifying that the operating parameters transmitted from the apparatus to the pump match the operating parameters returned from the pump to the apparatus.

However Blomquist, in an analogous art of configuring pumps for infusing fluids, teaches the missing limitations of generating the table (Fig. 8, element 810 and 812; i.e. table) on a user interface (pg. 6, lines 31-34 and pg. 7, lines 1-2), containing a row (Fig. 8, element 814 and 816; i.e. an array of the table), the row having a plurality of cells (i.e. fields), each cell in the row relating to a different operating parameter for the delivery program (pg. 16, lines 28-34 and pg. 17, lines 1-32; i.e. each field of the array in the table comprising one of a plurality of operating parameters); receive at least one operating parameter directly from the data entry device (pg. 3, lines 31-32, pg. 5, lines 29-32, pg. 6, lines 34, pg. 7, line 1-2, pg. 16, lines 28-34, pg. 17, lines 1-32 and Fig. 1, element 104; i.e. the user entering an operating parameter via input devices into one of a plurality of fields of the array); returning the operating parameters over a communication link from the pump back to the computer (pg. 24, lines 6-15); and verifying that the operating parameters transmitted from the computer to the pump match the operating parameters returned from the pump to the computer (pg. 24, lines

6-15) for the purpose of generating and verification of operational data that is download to an infusion pump (Blomquist: pg. 3, lines 31-34 and pg. 4, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Estes to include the addition of the limitations of generating a table on a user interface, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; receive at least one operating parameter directly from the data entry device returning the operating parameters over a communication link from the pump back to the apparatus; and verifying that the operating parameters transmitted from the apparatus to the pump match the operating parameters returned from the pump to the apparatus to eliminate the need for different pumps to be repeatedly programmed with the same sets of program data, thus providing efficiency and increased automation (Blomquist: pg. 1, lines 32-33 and pg. 2, lines 1-2).

19. As per claim 10, Estes teaches the processor is further programmed to generate a plurality of rows in the table rows (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Not explicitly taught is each row relating to a different set of operating parameter, each set of operating parameters defining a different delivery schedule for the pump.

The combination of Estes in view of Blomquist teaches each row (Fig. 8, element 816) relating to a different set of operating parameters (i.e. a record), each set of operating parameters defining a different delivery schedule for the pump (pg. 17, lines 5-32) for the purpose of generating and verification of operational data that is download to an infusion pump (Blomquist: pg. 3, lines 31-34 and pg. 4, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Estes to include the addition of each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump to eliminate the need for different pumps to be repeatedly programmed with the same sets of program data, thus providing efficiency and increased automation (Blomquist: pg. 1, lines 32-33 and pg. 2, lines 1-2).

20. As per claim 11, Estes teaches as set forth above each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

7. As per claim 26, Estes does not explicitly teach downloading further comprises transmitting an error signal over a communication link from the computer to the pump if verifying the operating parameters fails.

The combination of Estes in view of Blomquist teaches downloading further comprises transmitting an error signal over a communication link from the computer to the pump if verifying the operating parameters fails (pg. 24, lines 16-20) for the purpose of generating and verification of operational data that is download to an infusion pump (Blomquist: pg. 3, lines 31-34 and pg. 4, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Estes to include teaches downloading further comprises transmitting an error signal over a communication link from the computer to the pump if verifying the operating parameters fails to provide efficiency (Blomquist: pg. 1, lines 32-33 and pg. 2, lines 1-2).

6. As per claim 27, Estes does not explicitly teach downloading further comprises discarding the operating parameters transmitted from the computer to the pump and preserving operating parameters already stored into memory in the pump.

The combination of Estes in view of Blomquist teaches discarding the operating parameters transmitted from the computer to the pump and preserving operating parameters already stored into memory in the pump (pg. 24, lines 16-20) for the

purpose of generating and verification of operational data that is download to an infusion pump (Blomquist: pg. 3, lines 31-34 and pg. 4, line 1).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to modify the teaching of Estes to include teaches discarding the operating parameters transmitted from the computer to the pump and preserving operating parameters already stored into memory in the pump to provide efficiency (Blomquist: pg. 1, lines 32-33 and pg. 2, lines 1-2).

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 08 September 2011 and 09 September 2011 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer L. Norton whose telephone number is (571)272-3694. The examiner can normally be reached on Monday-Friday between 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert DeCady can be reached on 571-272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ramesh B. Patel/

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Primary Examiner, Art Unit 2121